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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO | |
|---------------------------------------|----------------|----------------------|---------------------|-----------------|--|
| 10/784,731 | 02/24/2004 | Arthur E. Colvin JR. | 2232-205 | 9477 | |
| 6449 7. | 590 03/17/2005 | | EXAM | EXAMINER | |
| ROTHWELL, FIGG, ERNST & MANBECK, P.C. | | | KREMER, MATTHEW J | | |
| 1425 K STREE | ET, N.W. | | | | |
| SUITE 800 | | | ART UNIT | PAPER NUMBER | |
| WASHINGTO | N, DC 20005 | | 3736 | | |

DATE MAILED: 03/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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|---|---|---|-------------|--|--|--|
| | Application No. | Applicant(s) | • | | | |
| Office Assis a Commence | 10/784,731 | COLVIN, ARTHUR E. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Matthew J Kremer | 3736 | | | | |
| The MAILING DATE of this communication app Period for Reply | ears on the cover sheet with the c | orrespondence address | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply if NO period for reply is specified above, the maximum statutory period who Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | 86(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days rill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE | nely filed s will be considered timely. the mailing date of this communication (35 U.S.C. § 133). | ation. | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on | _• | | | | | |
| 2a) This action is FINAL . 2b) ☐ This | This action is FINAL . 2b)⊠ This action is non-final. | | | | | |
| 3) Since this application is in condition for allowant closed in accordance with the practice under E | | | s is | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) 1-18 is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdraw | vn from consideration. | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>1-7,9-11 and 14-18</u> is/are rejected. | | | | | | |
| 7)⊠ Claim(s) <u>8,12 and 13</u> is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/or | r election requirement. | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examine | r. | | | | | |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ acce | epted or b) objected to by the B | Examiner. | | | | |
| Applicant may not request that any objection to the | drawing(s) be held in abeyance. See | e 37 CFR 1.85(a). | | | | |
| Replacement drawing sheet(s) including the correcti | ion is required if the drawing(s) is obj | ected to. See 37 CFR 1.12 | 21(d). | | | |
| 11) The oath or declaration is objected to by the Ex | aminer. Note the attached Office | Action or form PTO-152 | 2. | | | |
| Priority under 35 U.S.C. § 119 | | • | | | | |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau | s have been received. s have been received in Application ity documents have been receive | on No | ı | | | |
| * See the attached detailed Office action for a list of | of the certified copies not receive | d. | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) | 4) Interview Summary | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | Paper No(s)/Mail Da 5) Notice of Informal P | ate tatent Application (PTO-152) | | | | |
| Paper No(s)/Mail Date 6/10/2004. | 6) Other: | | | | | |

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DETAILED ACTION

Claim Objections

1. Claims 4 and 7 are objected to because of the following informalities. In claim 4, line 2, "a" before "indicator" should be "an". In claim 7, line 2, "a" before "indicator" should be "an". Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 3. Claims 17-18 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 6,179,767 to Ziegler et al. (Ziegler). Ziegler teaches an implanted sensor 3 with a PMMA shell 3g. (Fig. 2 of Ziegler).

Claim Rejections - 35 USC § 103

- 4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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- 5. Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,302,393 to Matsumoto et al. (Matsumoto) in view of U.S. Patent U.S. Patent 5,833,603 to Kovacs et al. (Kovacs)(cited by Applicant). Matusmoto teaches an implanted sensor (column 2, lines 30-50 of Matusmoto) made from polymethyl methacrylate (column 3, lines 14-34 of Matusmoto). Matusmoto does not teach the particulars of the implanted sensor. Kovacs teaches an implanted sensor (Abstract of Kovacs) that would fulfill the requirements of providing an implanted sensor set forth in Matusmoto. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the implanted sensor of Kovacs in the invention of Matusmoto since Matusmoto teaches the use of an implanted sensor and Kovacs teaches one such sensor.
- 6. Claims 1-7, 9, 11, and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent U.S. Patent U.S. Patent 5,833,603 to Kovacs et al. (Kovacs)(cited by Applicant) in view of U.S. Patent 5,730,125 to Prutchi et al. (Prutchi). Kovacs teaches a substrate (40), a first radiation source (60), a first detector (62 and 64), and a first indicator element (56 and 58). (Fig. 3 of Kovacs). Kovacs does not teach a second radiation source, a second detector, and a second indicator element on another side of the substrate. Prutchi teaches that using two sensing mechanisms on different sides of a substrate in an implanted device would eliminate effects due to

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lines 3-17 of Kovacs).

sensor motion. (Fig. 9 and column 11, lines 11-21 of Prutchi). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use two sensing mechanisms on different sides of a substrate in an implanted device as disclosed by Prutchi since effects due to sensor motion are eliminated. In regard to claim 1, the second sensing mechanism would include a second radiation source, a second detector, and a second indicator element. In regard to claim 2, LEDs are disclosed. (column 10, lines 56-65 of Kovacs). In regard to claim 3, a sensor body 44 is disclosed. (Fig. 3 of Kovacs). In regard to claim 5, a reference membrane 58 is disclosed. (Fig. 3 of Kovacs). In regard to claim 9, oxygen is determined. (column 10,

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7. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent U.S. Patent U.S. Patent 5,833,603 to Kovacs et al. (Kovacs)(cited by Applicant) in view of U.S. Patent 5,730,125 to Prutchi et al. (Prutchi) as applied to claim 4, and further in view of U.S. Patent 5,001,054 to Wagner. Kovacs teaches that that device is used to determine blood sugars. (column 3, lines 32-47 of Kovacs). Wagner teaches that glucose is one such blood sugar. (Abstract of Wagner). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to determine glucose since Kovacs teaches that blood sugars can be determined and Wagner teaches one such blood sugar.

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Allowable Subject Matter

8. Claims 8 and 12-13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter. In regard to claim 8, the prior art does not teach or suggest "said indicator molecules from said first and second indicator elements are affected by the presence or concentration of analytes that are different from one another" which is combined or combinable with the other limitations of claim 8. In regard to claim 12, the prior art does not teach or suggest "said first side of said substrate and said second side of said substrate contain regions that are masked" which is combined or combinable with the other limitations of claim 12.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew J Kremer whose telephone number is 571-272-4727. The examiner can normally be reached on Mon. through Fri. between 8:30 a.m. - 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew Kremer Assistant Examiner

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ERIC F. WINAKUR PRIMARY EXAMINER